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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/800,839	03/07/2001	Toshihiro Shimizu	2535US1P	7614

23115 7590 03/21/2005

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EXAMINER	
TRAN, SUSAN T	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 03/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

4C

Office Action Summary	Application No.	Applicant(s)	
	09/800,839	SHIMIZU ET AL.	
	Examiner	Art Unit	
	Susan T. Tran	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 January 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4-7,9-11 and 13-24* is/are pending in the application.

4a) Of the above claim(s) *22-24* is/are withdrawn from consideration.

5)☒ Claim(s) *10 and 11* is/are allowed.

6)☒ Claim(s) *1,2,4-7,9 and 13-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *01/20/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of applicant's Information Disclosure Statement, Request for Extension of Time, and Request for Continued Examination filed 01/20/05, Amendment and Declaration filed 10/14/04.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 01/20/05 has been entered.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 2, 4-7 and 13-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lundberg (US 6,132,770).

Lundberg teaches an effervescent tablet comprising mixture proton pump inhibitor (ppi) core (acid-labile active substance) and filler, binder, lubricant, disintegrant,

surfactant, other additives, and alkaline reacting agent (basic salt), including, calcium and magnesium salts (column 8, lines 55 through column 9, lines 1-5). Lundberg also teaches that the tablet having disintegrating time of about 55 seconds (see examples).

Lundberg is silent as to the teaching of the percent hydroxypropoxyl group, however, it is noted that Lundberg teaches a similar disintegration time using the hydroxypropyl cellulose in his effervescent tablet (see examples). Accordingly, it is the position of the examiner that Lundberg teaches the use of at least similar hydroxypropyl cellulose having the claimed hydroxypropoxyl group. Therefore, the burden is shifted to applicant to present data showing that the hydroxypropyl cellulose taught by Lundberg is different in nature. Thus, it would have been obvious for one of ordinary skill in the art to, by routine experimentation determine a suitable hydroxypropyl cellulose to obtain the claimed invention, because Lundberg teaches the use of hydroxypropyl cellulose in an effervescent tablet (rapidly disintegrable solid dosage form) to achieve a desirable rapid disintegration time.

Claims 1, 2, 4-7 and 13-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lundberg (US 6,132,770), in view of Watanabe et al. (Biol. Pharm. Bull. Vol. 18, No. 9).

Lundberg is relied upon for the reason stated above. Lundberg is silent as to the teaching of the disintegration time in one minute or less.

Watanabe teaches a rapid disintegrate compressed tablet comprising crystalline cellulose and low-substituted hydroxypropyl cellulose (L-HPC) (see page 1308, materials and methods section). The tablet which is rapidly disintegrated and dissolved in the mouth within 30 second, and having a crushing strength of 8-18 kgf (see page 1308, and page 1309, results and discussion section). Thus, it would have been obvious for one of ordinary skill in the art to prepare the effervescent tablet of Lundberg using crystalline cellulose and L-HPC in view of the teaching of Watanabe to obtain the claimed invention, because the references teach the advantageous results in the use of similar disintegrating agents for the same purpose, such as, Lundberg teaches the effervescent tablet is especially suitable for patients with swallowing disorders and in pediatrics (column 3, lines 53-55), and Watanabe teaches that it is necessary to develop a new type of tablet having the characteristics of rapid disintegration and dissolution in saliva suitable for elderly patients, and patients having difficulties or experience inconvenience in swallowing (see page 1308).

Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Makino et al. (US 5,501,861), in view of Watanabe et al. (Biol. Pharm. Bull. Vol. 18, No. 9).

Makino teaches a fast dissolving tablet comprising carbohydrate, and active agent including voglibose (see abstract; column 4, lines 42-43, 62-67; and column 5, lines 1-13). The composition further comprises other additives including disintegrators, binders, lubricants, and so on (column 5, lines 55-62).

Makino does not teach the use of low-substituted hydroxypropyl cellulose (L-HPC).

Watanabe teaches a rapid disintegrate compressed tablet comprising crystalline cellulose and low-substituted hydroxypropyl cellulose (L-HPC) (see page 1308, materials and methods section). The tablet which is rapidly disintegrated and dissolved in the mouth within 30 second, and having a crushing strength of 8-18 kgf (see page 1308, and page 1309, results and discussion section). Thus, it would have been obvious for one of ordinary skill in the art to prepare the fast dissolving tablet of Makino using crystalline cellulose and L-HPC as a disintegrator in view of the teaching of Watanabe to obtain the claimed invention, because the references teach the advantageous results in the use of similar disintegrating agents for the same purpose, such as, Makino teaches the fast dissolving tablet is suitable as a buccal dissoluble because of its easy solubility and disintegratability in the oral cavity (column 3, lines 9-11), Makino also teaches the fast dissolving tablet having adequate compressed strength (column 3, lines 25-26), and Watanabe teaches a new type of tablet having the characteristics of rapid disintegration and dissolution in the mouth without the need of water, as well as excellent compressed strength (see pages 1308 and 1310).

Response to Arguments

Applicant's arguments filed 01/20/05 have been fully considered but they are not persuasive.

Applicant argues that Lundberg, by contrast with the claimed invention teaches a multiple unit effervescent tablets that is dissolved and/or dispersed in an aqueous medium, such as drinking water. Contrary to the applicant's argument, the effervescent tablet taught by Lundberg is suitable for oral use (see column 1, lines 13-14). However, nothing in Lundberg prevent a patient from administering the effervescent tablet my mouth, and nothing in Lundberg indicating that the effervescent tablet will not disintegrate in a patient mouth, which also known to be an aqueous medium environment. Applicant's attention is called to column 3, lines 53-55, where Lundberg also recognizes the advantageous results desired by the applicant, namely, and effervescent dosage form suitable for patients with swallowing disorders and in pediatrics.

The Declaration under 37 CFR 1.132 has been fully considered, but is insufficient to overcome the rejection based upon Lundberg because: 1) the Declaration does not show a side-by-side comparison establishing that the tablet taught by Lundberg would not dissolve in a patient's mouth in one minute or less as being claimed; and 2) the amount of CO_2 evolved in a patient's mouth is not what being claimed. The Declaration refers only to the system described in the above referenced application and not to the individual claims of the application. Thus, there is no showing that the objective evidence of nonobviousness is commensurate in scope with the claims. See MPEP § 716. In view of the foregoing, when all of the evidence is considered, the totality of the rebuttal evidence of nonobviousness fails to outweigh the evidence of obviousness.

Claims Allowable

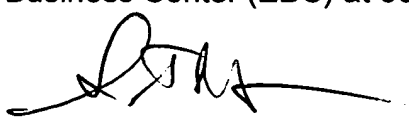
Claims 10 and 11 are allowed.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan T. Tran whose telephone number is (571) 272-0606. The examiner can normally be reached on M-R from 6:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page, can be reached at (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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